DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration
D1252B

San Francisco District
1431 Harbor Bay Parkway
Alameda, California 94502-7070
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CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Our Reference: 29-50592

March 11, 1997

Hillegonda Van Vliet
17782 South Seidner Road
Escalon, California 95320-9429

WARNING LETTER

Dear Ms. Van Vliet:

Tissue residue reports from the United States Department of Agriculture (USDA) and an investigation of your dairy on December 11 and 13, 1996 by Food and Drug Administration (FDA) Investigator Thomas W. Gordon have revealed serious violations of the Federal Food, Drug, and Cosmetic Act (the Act) as follows:

A food is adulterated under Section 402(a)(2)(D) of the Act if it contains a new animal drug that is unsafe within the meaning of Section 512 of the Act. On October 7, 1996, you consigned a cull dairy cow (identified by USDA laboratory report number 256412) to be slaughtered as human food. This cow, which was delivered for introduction into interstate commerce by your firm, was adulterated by the presence of illegal drug residues. USDA analysis of tissues from this animal revealed the presence of sulfamethazine in the liver tissue at 38 parts per million (ppm), and in the muscle tissue at 40 ppm. A tolerance level for sulfamethazine has been established for the edible tissue of cattle at 0.10 ppm.

A food is adulterated under Section 402(a)(4) of the Act "if it has been prepared, packed, or held under insanitary conditions...whereby it may have been rendered injurious to health." As it applies in this case, "insanitary conditions" means that you hold animals which are ultimately offered for sale for slaughter as food under conditions which are so inadequate that

medicated animals bearing possibly harmful drug residues are likely to enter the food supply. For example, our investigator noted the following:

1. You lack an adequate system for determining the medication status of animals you offer for slaughter.

2. You lack an adequate system for assuring that animals to which you administer medication have been withheld from slaughter for appropriate periods of time to deplete potentially hazardous residues of drugs.

3 You lack an adequate system for assuring animals have been treated only with drugs which have been approved for use in their class of animal or species.

4. You lack an adequate system for assuring that drugs are used in a manner not contrary to the directions contained in their labeling.

5. You lack an adequate system for determining that quantities of drugs are being accounted for to prevent the possible overdosing of animals.

The Sulfa-Max III brand of sulfamethazine boluses that you use to treat your dairy cows are adulterated under Section 501(a)(5) of the Act in that they are new animal drugs within the meaning of Section 201(w) and are unsafe within the meaning of Section 512(a)(1)(B) of the Act since they are not being used in conformance with approved labeling. Labeling directions specify that the product is not to be used to medicate dairy cattle twenty months of age or older, and animals intended for human consumption must not be treated within twelve days of being slaughtered. Failure to adhere to the labeling directions for Sulfa-Max III is likely the cause of the illegal residues of sulfamethazine in the cow you sold for food use.

Your practice of mixing 25 milliliters (mls.) of Tetra-Bac 324 brand of tetracycline hydrochloride soluble powder with water to prepare a uterine infusion for use in your lactating dairy cattle is an unapproved use for which safety and efficacy have not been proven. Creating the infusion constitutes manufacturing a new animal drug which requires the submission of a New Animal Drug Application for FDA approval. Labeling for Tetra-Bac 324 states the product is to be administered orally for calves and does not allow for its use in lactating dairy cows.

Your practice of mixing 5 mls. of Oxy-Tet 100 brand of oxytetracycline hydrochloride injection with 50 mls. of water to prepare a uterine infusion for use in your lactating cattle is an unapproved use for which safety and efficacy has not been proven. Creating this infusion also constitutes manufacturing a new animal drug which requires the submission of a New

Animal Drug Application for FDA approval. Labeling for Oxy-Tet 100 states that it is to be administered intramuscularly in cows and specifically states the product is not for use in lactating dairy cattle.

Your use of Cefa-Lak brand Mastitis Tubes is not in conformance with approved labeling when you use two tubes per quarter the first day and one tube per quarter thereafter. The product labeling states that one tube per quarter is to be used. A second tube may be used after a twelve hour period has elapsed. A maximum of two tubes may be used.

Your use of the drug Agricillin brand penicillin G procaine is not in conformance with its approved labeling directions. Labeling for penicillin G procaine requires a dosage of 1 ml. per 100 pounds of body weight with no more than 10 mls. injected into one site. Your practice of administering up to 25 mls at a dosage of 12.5 mls in two sites in your dairy cows results in a dosage in excess of that allowed by the labeling.

Use of a drug in a species or class of animal for which they are not intended, coupled with a failure to heed full slaughter withdrawal times, presents a likely possibility that illegal residues will occur. Your use of drugs for treating your dairy cows does not conform to the labeling instructions. Failure to comply with the label instructions on drugs used to treat animals makes the drugs unsafe.

We request that you take prompt action to ensure that animals which you offer for sale as human food will not be adulterated with drugs or contain illegal residues.

Introducing adulterated foods into interstate commerce is a violation of Section 301(a) of the Act.

Causing the adulteration of drugs after receipt in interstate commerce is a violation of Section 301(k) of the Act.

You should be aware that it is not necessary for you to have personally shipped an adulterated animal into interstate commerce to be responsible for a violation of the Act. The fact that you offered an adulterated animal to be slaughtered into food for human consumption where it was held for sale in interstate commerce is sufficient to make you responsible for violations of the Act.

Your firm has established a history of offering animals for sale for human food use which have been found to be adulterated with drug residues. According to USDA analytical reports during the period of February 5, 1993, through October 7, 1996, your firm sold two cows which contained violative levels of tetracycline, oxytetracycline, and sulfamethazine. An

inspection was conducted of your dairy on August 20, 1992. During the inspection you were warned that it is illegal to market animals with illegal levels of antibiotics in tissue residues. A Warning Letter, dated November 13, 1992, was sent to your firm as a result of the violations found during the inspection. Also, the U.S. Department of Agriculture has sent you letters for the animals in which USDA analysis found violative levels of drug residues. You have failed to take adequate corrective action. It is your responsibility to ensure that all requirements of the Act and regulations are being met. Failure to achieve prompt corrective action may result in enforcement action without further notice, including seizure and/or injunction.

Within fifteen (15) days of the receipt of this letter, notify this office in writing of the specific steps you have taken to correct these violations and preclude their recurrence. If corrective action cannot be completed within fifteen working days, state the reason for the delay and the time frame within which corrections will be completed. Your response should address each discrepancy brought to your attention during the inspection and in this letter, and should include copies of any documentation demonstrating that corrections have been made. Please direct your reply to Thomas W. Gordon, Investigator.

Sincerely yours,

for Patricia C. Ziobro
District Director
San Francisco District

cc: [redacted]